ABSTRACT

Methods of inducing an immune response which protects a susceptible animal subject from lethal infection with *Bacillus anthracis* (*B. anthracis*) are provided. One method comprises administering an effective amount of wild-type, or preferably a mutated form of, *B. anthracis* lethal factor (LF) or an immunogenic fragment thereof to the subject. A second method comprises administering an effective amount of a mutated LF protein or an immunogenic fragment of an LF protein and an effective amount of the *B anthracis* protective antigen (PA) or an immunogenic fragment of the PA protein to the subject A third method comprises administering a polynucleotide or nucleic acid comprising a sequence encoding a mutated *B. anthracis* LF protein or an immunogenic fragment of an LF protein to the subject. A fourth method comprises administering a polynucleotide which comprises a coding sequence for a mutated LF protein or an immunogenic fragment of an LF protein and a polynucleotide which comprises a coding sequence for the *B. anthracis* PA protein or an immunogenic fragment thereof to the subject. The present invention also relates to a protein or peptide based-immunogenic composition for preparing a vaccine which is capable of prophylactically protecting a subject against lethal effects of infection with *B. anthracis* or exposure to a toxic agent which is produced by *B. anthracis*. The protein or peptide based immunogenic composition comprises a purified or recombinant LF protein or immunogenic fragment thereof and a purified or recombinant PA protein or immunogenic fragment thereof. The present invention also relates to a nucleic acid-based immunogenic composition comprising a nucleic acid which comprises a sequence encoding the LF protein or an immunogenic fragment thereof and a polynucleotide which comprises a sequence encoding the PA protein or an immunogenic fragment thereof.